Notice of Allowability	Application No.	Applicant(s)	
	09/641,104	BIRCHMEIER ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *2/18/05*.

2. ☒ The allowed claim(s) is/are *44,45,47,48 and 50*.

3. ☒ The drawings filed on *20 August 2003* (August 17, 2000) are accepted by the Examiner.

4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☒ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 1/10/05
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20050516*.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with David Saliwanchik on May 19, 2005.

Examiner's Amendments to the specification:

-Please replace the paragraph (A_1), which is inserted by preliminary amendment filed August 17, 2000, at page 1 after the title with the following paragraph:

This application is a continuation of International Application No. PCT/DE99/00554, filed February 21, 1999, which claims priority of German Patent Application No. 198 07 390.9, filed February 21, 1998, the contents of which are incorporated herein by reference thereto.

-Please replace the third paragraph at page 11 with the following paragraph:

Fig. 2:

Characterization of the minimum binding domain of TCF-4 (residues 1-18 of SEQ ID NO:3) by inhibition of binding of β-catenin to LEF-1 in an ELISA.

-Please replace the phrase "Comparison of the minimum binding domains of LEF-I and TCF-4 with the respective positions of the amino acids." at page 12, paragraph 3 with the phrase "Comparison of the minimum binding domains of LEF-I (SEQ ID NO:2) and TCF-4 (SEQ ID NO:4) with the respective positions of the amino acids."

-Please replace the term "Fig. 5:" at page 12, paragraph 4 with the term "Figs. 5a-5e:"

-Please replace the paragraph describing Fig. 8 at page 4 of the amendment to Specification filed August 20, 2003 with the following paragraph:

Figs. 8A and 8B:

Substances binding in the hydrophobic pocket of β-catenin.

Representation of the surface of the hydrophobic pocket region (Grasp). The amino acid residues of the essential binding site for LEF/TCF are marked in blue color (for mutations blocking the interaction between β-catenin and LEF/TCF: Lys 435, Arg 469 and His 470). In the β-catenin molecule one of the low-molecular substances binding in the pocket is represented.

-Please replace the second paragraph describing Tab. 1 at page 13 with the following paragraph:

Tab. 1:

Amino acid sequence of the armadillo repeats 3-8 of human β-catenin: arm 3 (SEQ ID NO:6), arm 4 (SEQ ID NO:7), arm 5 (SEQ ID NO:8), arm 6 (SEQ ID NO:9), arm 7 (SEQ ID NO:10), arm 8 (SEQ ID NO:11) and arm 9 (SEQ ID NO:12).

- Please replace the Tab. 4 filed August 20, 2003 with the replacement sheet of Tab. 4 (see attached 4 pages):

Examiner's Amendments to the Claims:

Claims 45, 47 and 50 have been amended as follows:

45. (Currently amended) A peptide or polypeptide obtained from the armadillo domain of human β-catenin polypeptide which inhibits the interaction of human β-catenin polypeptide and a transcription factor or tumor suppressor protein, wherein said peptide or polypeptide is selected from the group consisting of peptides or polypeptides consisting of the sequences shown in SEQ ID NO: 6 having a mutation in Phe in position 30, ~~or~~ a mutation in His in ~~position37~~ position 37 or both; SEQ ID NO: 7 having a mutation in Arg in position 9, ~~or~~ a mutation in Lys in position 27 or both; SEQ ID NO: 8 having a mutation in Trp in position 32, ~~or~~ a mutation in Arg in position 36, ~~or~~ a mutation in Lys in position 39 or any combination of mutations thereof; SEQ ID NO: 9 having a mutation in Lys in position 5, ~~or~~ a mutation in ~~TRP~~ Trp in position 34, ~~or~~ a mutation in Arg in position 37 or any combination of mutations thereof; SEQ ID NO: 10 having a mutation in Lys in position 4; and SEQ ID NO: 11 having a mutation in Lys in position 6, ~~or~~ a mutation in Arg in position 28, ~~or~~ a mutation in Arg in position 40, ~~or~~ a mutation in His in position 41 or any combination of mutations thereof, wherein said mutation replaces the indicated amino acid with an aliphatic amino acid.

47. (Currently amended) The peptide or polypeptide according to claim [[44]] 45, wherein said mutation replaces the indicated amino acid with alanine, valine, leucine or isoleucine.

50. (Currently amended) The peptide of claim 47, wherein ~~the effect is to inhibit the~~

~~interaction of β-catenin and~~ said transcription factor or tumor suppressor protein is selected from the group consisting of lymphoid enhancer-binding factor-l (LEF-1), T cell transcription factor-l (TCF-1), 15 amino acid repeats of adenomatous polyposis coli ~~15~~ (APC-15), conductin, E-cadherin and 20 amino acid repeats of APC (APC-20).

The following is an **Examiner's Statement of Reasons for Allowance**: The following reference appears to be the closest art to the claimed invention: Huber *et al.* (Cell 90, 871-882 (September 7, 1997)) disclose the three dimensional structure of the armadillo repeat region of murine β-catenin, designated β-59, and its two 40 and 10 kDa fragments consisting of residues 134-550 and 551-671. However, the reference does not teach or suggest a polypeptide consisting of the sequence of SEQ ID NO: 6-11 or 12 (arm 3-9 of human β-catenin), or specific mutants thereof. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

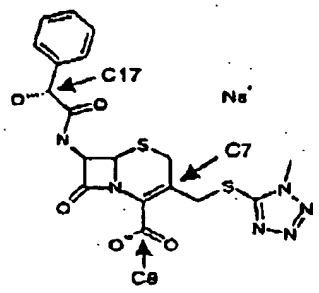
Chih-Min Kam, Ph. D. CMK
Patent Examiner

CMK
April 7, 2005

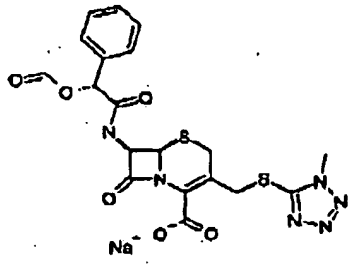
JON WEBER
SUPERVISORY PATENT EXAMINER

Tab. 4 Positive List

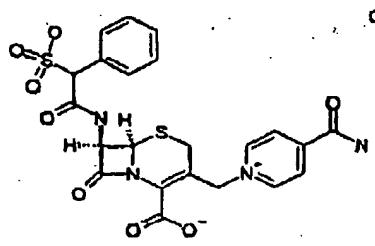
Molecule Class **IA (Inhibitors of the Cefamandole-type)**



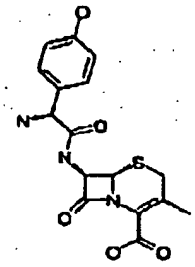
Cefamandole



Cefamandole-Nafate

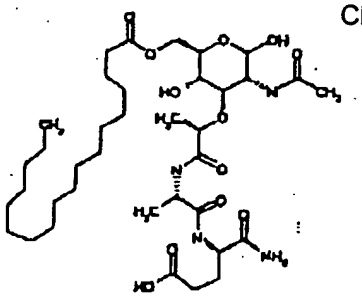


Cefsulodin



Cefadroxil

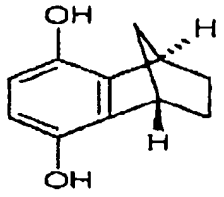
Molecule Class **IB**



AC-(6-O-STEAROYL)-MURAMYL-ALA-D-ISOGLUTAMINE

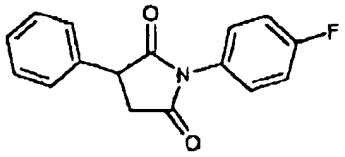
Positive List

Molecule Class IC



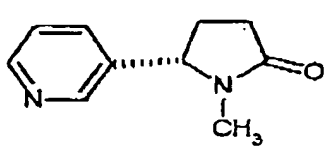
3,6-DIHYDROXYBENZONORBORNANE

Molecule with Modulating Activity for Molecule Class 1

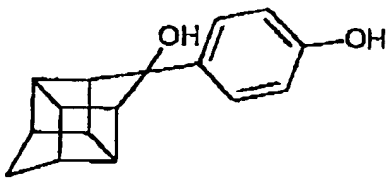


1-(4-FLUOROPHENYL)-3-PHENYLPYRROLIDINE-2,5-DIONE

Chiral



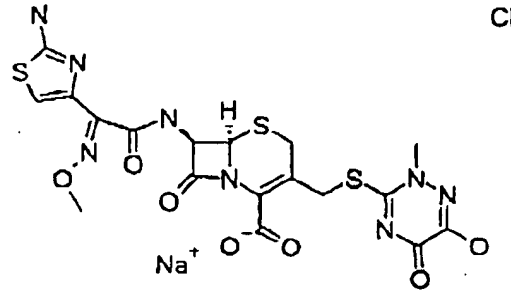
(-)-COTININE



4-(2-HYDROXYOCTAHYDRO-1,3,4-METHENO-
2H-CYCLOBUTA(CD)PENTALEN-2-YL)PHENOL

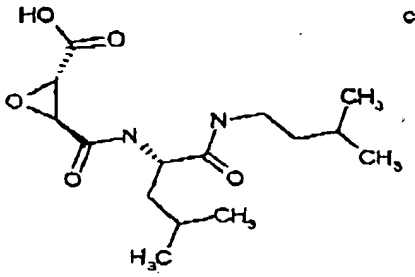
Positive List

Chiral



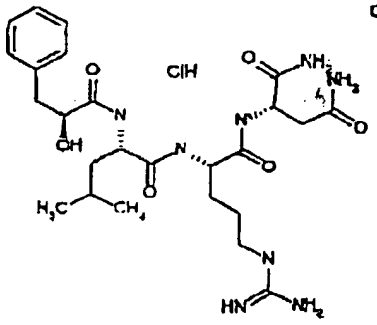
Cefatriaxone

Chiral



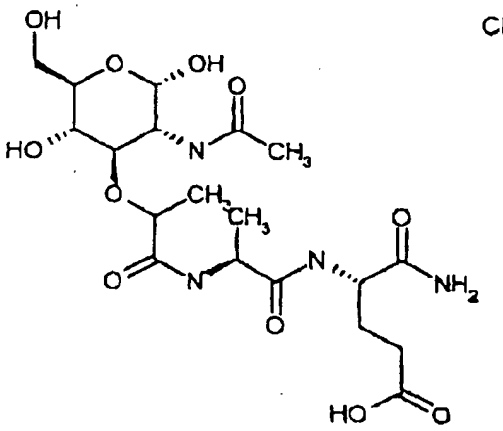
L-TRANS-EPOXYSUCCINYL-LEU-3-METHYLBUTYLAMIDE

Chiral



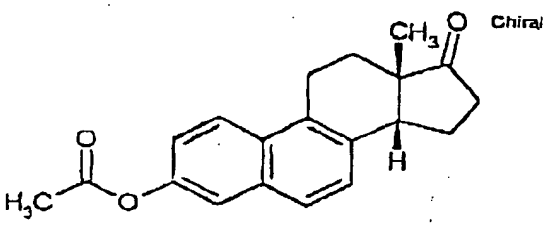
ANTHO-RNAMIDE

Positive List



Chiral

N-ACETYL-MURAMYL-ALA-ISOGLN-OH



Chiral

1,3,5(10),6,8(14BETA)-ESTRAPENTAEN-3-OL-17-ONE ACETATE